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December 17, 2013

Redacted by agreement
Vice Chancellor for Research and Dean of the Graduate School
University of Wisconsin
333 Bascom Hall
500 Lincoln Drive
Madison, WI 53706-1380

Dear Redacted by agreement

We are writing in regard to two incidents involving recombinant research with highly pathogenic avian influenza (HPAI) H5N1 that have occurred recently in the ABSL3+ laboratory of Dr. Redacted by agreement After reviewing the details of these two incidents, NIH has significant concerns relating to the University of Wisconsin's apparent lack of a dedicated quarantine facility other than the researcher's home. We also have concerns relating to the biosafety practices associated with these incidents. Our concerns are detailed below.

Lack of a dedicated quarantine facility

In the needlestick incident that occurred on November 16, 2013, a decision was made to home quarantine the individual because the route of exposure (needlestick) was not expected to place the researcher at high risk for infection and this influenza strain, which contained the HA gene from H5N1, was determined not to be a mammalian-transmissible strain. However, in conversations with the University of Wisconsin Alternate Responsible Official, Redacted by agreement Redacted by agreement regarding this incident Redacted by agreement informed us that all researchers exposed to H5N1 would be quarantined at home, regardless of the risk of infection or whether the strain was mammalian-transmissible or not.

In a subsequent phone conversation with the University of Wisconsin Senior Associate Dean for Research, Redacted by agreement the policy for home isolation for all incidents was reiterated to us. We were told by Redacted by agreement that the decision was based upon consultation with University of Wisconsin infectious disease experts and the state health department. We were also informed that the use of a hospital room for quarantine was rejected due to the stress it would place on the laboratory worker.

The University of Wisconsin's policy on home quarantine communicated to us by Redacted by agreement Redacted by agreement s not in keeping with what was communicated to us in Redacted by agreement application to the Department of Health and Human Services to perform research with mammalian transmissible strains of HPAI H5N1. In a May 6, 2013, plan provided to NIH, Dr. Redacted by agreement indicated that he had access to a "designated quarantine apartment" in which researchers could be placed for 10-14 days in the event of an accidental exposure (Attachment A). Redacted by agreement have indicated to OBA that there was a miscommunication between the PI and the University of Wisconsin administration regarding the availability and appropriateness of such a quarantine apartment.

The University of Wisconsin's policy on home quarantine is inconsistent with the requirements for this research under the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*), and under the terms agreed to by the University as a condition of funding this project. **The University of Wisconsin must find a dedicated facility outside of the individual's permanent residence (1) in which an individual exposed to mammalian-transmissible HPAI H5N1 can be safely isolated for up to 10 days, and (2) that can be decontaminated easily after the individual's departure.** An isolation room in a hospital would also be appropriate. An individual's permanent residence is not appropriate when the risk of infection is high. For high risk exposures, it is critical to isolate the individual in a structure that does not have shared air exchange and can be quickly and efficiently decontaminated in the case of infection. In addition, if this structure is outside of a health care facility, there needs to be a plan in place regarding how this researcher could be safely transported to an isolation room in a health care facility, should he or she develop clinical symptoms, without the risk of exposure to other individuals.

<u>Concerns relating to biosafety practices</u>

In addition to the quarantine issue, NIH has significant concerns regarding the biosafety practices associated with both of the recent incidents.

The November 16, 2013, needlestick incident occurred when the researcher used a needle to collect tissue culture supernatant in violation of the University of Wisconsin's own policies, which only permits needles to be used in the ABSL3+ laboratory to anesthetize research animals, draw blood from research animals, or inoculate eggs. It was unclear from the University's response why this individual was using a needle for this type of procedure.

The University of Wisconsin report regarding the November 9, 2013, HPAI H5N1 spill described the researcher as having two to three inches of exposed skin between where his tyvek suit ended and his shoe covers began. While it was reported that none of the spilled material landed on the researcher's bare skin, we made it clear in our letter (Attachment A) and in a phone conversation with Redacted by agreement that having bare skin in the ABSL3+ laboratory was unacceptable under the containment requirements for this research specified in the *NIH Guidelines*. During that phone conversation, Redacted by agreement stated that the ABSL3+ laboratory had recently undergone a Select Agent inspection and the report from that inspection did not specifically mention a prohibition against working in the ABSL3+ laboratory

with bare skin. We have discussed the issue of bare skin in the ABSL3+ laboratory with the United States Department of Agriculture (USDA) Select Agent Program, and they are in agreement that bare skin is unacceptable at this level of containment.

Attachments B and Attachment C to this letter contain the NIH response to both H5N1 incidents. These letters contain requests for action regarding the quarantine situation and our biosafety concerns. We would appreciate any assistance you can provide to ensure that these requests are answered by December 23, 2013.

Finally, if your response is not received by this date or if does not fully address the issues we have described regarding a dedicated quarantine facility and inappropriate biosafety practices, as required by the terms and conditions of grant award, NIH will institute enforcement action(s) for the NIH grant Redacted by agreement Redacted by agreement Principal Investigator. Such actions could include disallowance of costs, suspension, or termination of the grant award.

If you have any questions, please feel free to contact us.

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cc: Redacted by agreement

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